



Contact Information

Shenzhen XFT Electronics Co., Ltd

Add: Building B, North Area, Linpishan Industrial Zone, Huangpu Road,
Shajing Street, Bao'an District, Shenzhen, China (Postal code: 518125)

Tel: (86)-755-29888818

Fax: (86)-755-27337797

<http://www.xft-china.com>

Email: sales1@xft.cn

EC/REP: ShangHai International Holding Corp. GmbH (Europe)

Add: Eiffestrasse 80 D -20537 Hamburg Germany



Foot Drop System | XFT-2001 |

User Manual

XFT-2001 Foot Drop System User Manual

Contents

Introduction to Your XFT-2001 System	1
1. Introduction	1
2. Indications of Use	1
For Your Health and Safety	2
General Overview of Your XFT-2001	5
1. Components of the XFT-2001	5
2. XFT-2001 Cuff and Stim Unit	6
3. Foot Sensor	7
Operating Modes	8
1. Gait Mode	8
2. Training Mode	8
Daily Use of Your XFT-2001	9
1. Installing and Replacing the Batteries	9
2. Installing the Stimulation Unit onto the Cuff	10
3. Connect and Replace the Electrode Pads	10
4. Identify Initial Placement of the Electrode	11
5. Positioning the Cuff on Your Leg	15
6. Activating and Using the System	16
7. Taking the Cuff OFF	20
8. Skin Care	20
Care and Maintenance	21
1. Stim Unit and Cuff	21
2. Electrodes	22
Frequently Asked Questions	23
Wearing Times	25
Specifications	26

Packing & Shipping Requirements



Be careful while the goods being packed and shipped
Frangible



Keep upwards while the goods being shipped or packed.
Upwards



Prevent from being wet or rainy
No Rain



The maximum weight of being piled is 80 KG
Maximum Weight of being piled



The maximum layer of being piled is SIX
Maximum Layer of being piled



: Date-Month-Year



: Shenzhen XFT Electronics Co.,LTD.



Building B, North Area, Linpishan Industrial Zone, Huangpu Road,
Shajing Street, Bao'an District, Shenzhen, China (Postal code: 518125)

Temperature range for transport and reservation: 5 ~ 40°C

Relative humidity range for transport and reservation: ≤ 80 %

Air pressure range for transport and reservation: 70Kpa to 106 Kpa

Introduction to Your XFT-2001 System

1.Introduction

The XFT-2001 is a battery-operated, electrical stimulator that can be used for functional electrical stimulation (FES). Central nervous system injuries often cause a gait disorder called "Foot Drop" which is the inability to raise the foot while walking and therefore results in dragging of the foot, instability and increased effort during gait. The XFT-2001 is an advanced neuroprosthesis designed to improve gait in people suffering from foot drop as a result of a central nervous system injury or diseases such as stroke, traumatic brain injury, multiple sclerosis, cerebral palsy or incomplete spinal cord injuries. The XFT-2001 System Patient Kit consists of a Cuff, a Functional Stimulation Unit (Stim Unit), a Foot Sensor and electrodes. The Stim Unit and Foot Sensor communicate wirelessly, thus enabling easy and comfortable use without cumbersome wires. The XFT-2001 delivers electrical pulses to the Peroneal Nerve which controls the movement of the lower leg muscles, causing them to raise the foot at the appropriate phase of walking and therefore prevents foot drop.

The Cuff can be used easily and its advanced ergonomic design ensures constant and snug contact between the user's limb and its integrated Electrodes. The Functional Stimulation Unit displays information regarding the system's status and manages the various system components. Please read this guide carefully in order to maximize the benefits provided by this advanced system.



FES Control Unit with Cuff

Foot Sensor

2.Indications of Use

The XFT-2001 is intended to provide ankle dorsiflexion in individuals with foot drop following an upper motor neuron injury or disease (such as a stroke, traumatic brain injury, multiple sclerosis, cerebral palsy or incomplete spinal cord injuries). During the swing phase of gait, the XFT-2001 electrically stimulates common peroneal nerve which innervates the tibialis anterior and other muscles in the affected leg to provide dorsiflexion of the foot; thus, it may improve the individual's gait. The XFT-2001 may also facilitate muscle re-education, prevent/retard disuse atrophy, maintain or increase joint range of motion and increase local blood flow.

For Your Health and Safety

Contraindications

- Do not use on persons with implanted demand type cardiac pacemakers or defibrillators.
- Do not place the electrodes in the carotid sinus region (throat). Laryngeal or pharyngeal spasms may occur when the electrodes are placed across the throat or in the mouth.
- Do not place the electrodes over malignant tumors.
- Do not place the electrodes over areas in which symptoms of existing thrombosis are present.
- Do not use if person has a history of seizure disorder.

Warnings about Functional Electrical stimulation (FES)

- The use of XFT-2001 may interfere with the proper functioning of electronic monitoring equipment such as EKG machines. However, the operation of the XFT-2001 device will not be affected by the use of electronic monitoring equipment.
- The XFT-2001 should not be worn while receiving an MRI scan.
- The use of electrodes not supplied by XFT Company may diminish results or increase risk of burns or discomfort. Do not place electrodes over open wounds, broken skin or metal objects beneath the skin such as surgical staples.
- The safety of XFT-2001 for use during pregnancy has not been established.
- Do not use simultaneously with high frequency hospital equipment (e.g. diathermy equipment). It may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Improper or prolonged use of electrodes may result in increased risk of skin irritation or burns and decreased effectiveness. Infrequently, there is an allergic response to the electrode adhesive or gel. Do not place electrodes on skin which is already irritated as this will increase the risk of discomfort with stimulation or skin burns.
- As a FES device, XFT-2001 Foot Drop System should be used under the medical supervision of a physician and a qualified clinician.
- Care should be taken while using XFT-2001 therapy in close proximity (e.g. less than 1 meter) to devices which emit radio frequencies such as cellular phones or two-way radios as some types of transmitters may cause undesirable stimulation to the user.
- External defibrillation of a person wearing a FES device can damage the device or injure the patient even when the device is turned off. Under some circumstances there may be risk of burns under the electrode sites during defibrillation. To eliminate any risk, the FES electrodes should be removed before defibrillation paddles are applied.
- Effects of long term chronic stimulation are unknown in this particular application.

Foot Sensor

Size of Transmitter:	47mm (H) x 40mm (W) x 21mm (T)
Weight:	27g
Battery Type:	DC 3.6V, Coin cell, LIR2450
Shipping and Storage Conditions:	Transport and storage temperature: -20°C ~ 55°C Operating conditions temperature: 5°C ~ 40°C Humidity: 80% max., non-condensing Atmospheric pressure: 70 Kpa ~ 106 KPa

Electrodes

Conductive adhesive electrode, diameter 50mm

Transport and storage temperature (Long Term): 5°C ~ 27°C

Relative Humidity: 35% ~ 50%

Atmospheric pressure: 70 Kpa ~ 106 KPa

Transport and storage temperature (Short Term: Less than one month): 0 ~ 40°C

Relative Humidity: 35% ~ 50%

Atmospheric pressure: 70 Kpa ~ 106 KPa


Other Accessories

Instruction manual
Coin cell (Rechargeable)
Coin cell charger
Electrode lead
USB wire

※ Do not hesitate to contact your clinician should you have any questions regarding this device and its safe operation and use.

Specifications

Stim Unit

Classification:	Type BF Equipment 
Size:	99mm (H) x 65mm (W) x 20mm (T)
Weight:	50g
Power Source:	Two 1.5 V Alkaline AAA battery
Maximum Current:	150 mA
Max Voltage:	100V
Load impedance:	500 Ω
Number of Operation Modes:	2 (Training, Gait)
Pulse Width:	25-300 microseconds (Adjustable)
Pulse Type:	Asymmetrical Biphasic
Frequency Range:	16-33Hz (Adjustable)
Stimulation Trigger Source:	Tilt or Foot Sensor
Controls and Indicators:	ON/OFF/Intensity; Stimulation, Gait/Training mode, Error
Shipping and Storage Conditions (Long Term):	Transport and storage temperature: -20°C ~ 55°C Operating conditions temperature: 5°C ~ 40°C Humidity: 80% max., non-condensing Atmospheric pressure: 70 Kpa ~ 106 KPa

Cuff (Adult or Child, and left or right for choice)

Size:	Adult: 290mm (L) x 135mm (W) x 15mm (T) Child: 200mm (L) x 95mm (W) x 10mm (T)
Weight:	Adult: 124g Child: 50g

Wireless Link

Communication Standard:	Bluetooth 2.0
Frequency Band:	2.402 — 2.480GHz

Specific Warnings

- Care should be taken when using the XFT-2001 for people who experience dizziness or have difficulty maintaining balance. The XFT-2001 is not designed to prevent falling.
- The user should obey doctor's advice to relocate the position of the electrodes within the cuff. Do not use the XFT-2001 without electrodes.
- Never use the XFT-2001 on any area of the body other than the leg.
- Stop using the XFT-2001 if stimulation does not come on at the appropriate time when walking and/or there is a change in the sensation perceived while the stimulation is on.
- XFT-2001 is not intended for use within flammable environments such as oxygen and anesthetics.
- Care should be taken to minimize excessive impact to the XFT-2001 Control Module. This includes standing or kneeling on the unit, or impact from any hard surfaces.

Precautions

- Use caution in applying electrical stimulation to persons suspected of having heart disease. More clinical data is needed to show that such persons will not experience adverse results.
- Use caution when placing electrodes on areas of the skin with reduced response to normal sensory stimuli, due to the risk of skin burns.
- XFT-2001 devices should be kept out of the reach of children.
- Use caution in applying electrical stimulation to persons suspected of having epilepsy. More clinical data is needed to show that such a person will not experience adverse events.
- Do not use XFT-2001 following recent surgery where muscle contraction may disrupt the healing process.
- Do not use lotion or oil in the area that the electrodes make contact with the skin. Stimulation may not be effective.
- The safety and efficacy of XFT-2001 depends on the proper use and handling of the system. Improper use of the device or electrodes can result in injury to the patient. Regularly check accessories for wear and replace as needed. Electrodes should be firmly secured to the skin.

- Never use the XFT-2001 if it appears to be malfunctioning. If there is a change in the way it usually works (i.e. change in sensation, surging of stimulation, intermittent stimulation) do not use the XFT-2001 and contact your clinician immediately.
- The XFT-2001 should be used with Electrodes supplied by Shenzhen XFT Electronics Co., Ltd.
- The stimulator should not be used while operating potentially dangerous equipment such as automobiles, power lawn mowers or large machinery. Abrupt changes in stimulation level could create a hazard.
- The XFT-2001 should not be worn or used while sleeping or bathing.
- The use of heat or cold producing devices such as electric blankets, heating pads or ice packs may affect the electrodes or the person's circulation and increase the risk of injury. A medical doctor and clinician should be consulted before using with XFT-2001.
- Medical electrical equipment needs special precautions for electromagnetic compatibility. This product conforms to standards IEC60601-1-2 of EMC.

Adverse Reactions

- Skin irritation and burns beneath the electrodes have been reported with the use of surface functional electrical stimulation devices. Do not leave the electrodes in place for long periods of time without checking or cleaning the skin underneath them. It is normal to observe somewhat reddened areas under the electrode placements. However, the redness should disappear within an hour. Signs of irritation are maintained redness, small pimple-like lesions or blisters. DO NOT continue stimulation over irritated skin.

※ Notify the medical doctor if these conditions persist and discontinue use of the XFT-2001 until the problem is resolved.

Wearing Times

	ON Time	OFF Time
Day 1-3	15-60 minutes	30 minutes
Day 4-6	1-3 hours	30 minutes
Day 7-9	3-5 hours	30 minutes
Day 10-12	5-6 hours	1 hour
Day 13-14	6-8 hours	1 hour

Helpful Hints:

- Remove the XFT-2001 Foot Drop System every 2 hours to check skin integrity.
- Slowly work into full-time wearing of the XFT-2001 Foot Drop System.
- Remove the cuff at regular intervals and inspect the skin under the electrodes. These areas will be pink due to increased blood flow under the electrodes.
- DO NOT use lotions or oils to soften the skin. Make sure the skin is clean and dry prior to applying the cuff.
- If desired, shaving the leg should be done in the evening to prevent potential irritation during daily wear.
- If soreness or irritation occurs in the area under the electrodes, reduce the wearing time and contact your clinician.
- Wet the electrodes with plenty of water before applying the cuff. Make sure you change the electrodes approximately every 1-2 weeks, and cover them each night with the plastic backing tabs.
- The battery can be continuous used about 10 hours (About 20 days, 30 minutes per day), replace the battery while out of energy or low battery.

10) Why doesn't the stimulation come on at the appropriate time?

This generally indicates the cuff may have shifted or a change in the walking pattern. Discontinue use and schedule an appointment with the clinician so that appropriate adjustments can be made to the XFT-2001.

11) Is it okay to use lotion or oils on the leg?

No—do not apply lotions or oils to the leg in the area of the electrodes. Clean the area under the electrodes each day with a mild soap and water. Make sure the leg is clean and moist at the electrode site before applying the XFT-2001.

12) What should I do to lift the foot higher?

If the foot slightly drags or catches on the floor while walking or if the stimulation is unpleasant, the stimulation level can be increased by tuning the blue knob in a clockwise position until at the right level. Adjust the intensity to the level determined by the clinician. Higher levels of stimulation may result in discomfort or skin irritation.

13) What should I do to decrease the foot lift?

If your foot rises too high while walking or if the stimulation is unpleasant, the intensity level can be reduced by tuning the knob in an anti-clockwise position until at the right level. Be sure that your foot does not drag or catch on the floor after reducing the intensity level.

General Overview of Your XFT-2001

1. Components of the XFT-2001

The patient kit is supplied with the following components:



- ① Carrying Case
- ② Coin Cell
- ③ Electrodes Pads
- ④ Foot Sensor
- ⑤ Coin Cell Charger
- ⑥ Charger Lead
- ⑦ Cuff & Stim Unit

2. XFT-2001 Cuff and Stim Unit

The Stim Unit is integrated on the Cuff. It can be slide onto the Cuff or slide out from the Cuff. Two Electrodes are attached to the inner lining of the Cuff. Their position in the Cuff has been carefully determined by the clinician during the fitting process. The Electrodes can be easily replaced by the user.



Intensity Knob /Off: Adjust electrical stimulation intensity and turn on/off device.

Training/Gait: Working mode switch.

Status LED: Yellow light will brighten when there has stimulation.

Composite Key: While in Gait Mode, press and hold it will have continuously stimulation. It can be used to check the placement of the electrode pad is accurate or not. It also can be used to select training level (Level 1 to 5) in Training Mode.

Location Label: To make the cuff on the right place (The location label align with the tibia).

USB Interface: The interface is for standby application.

Electrode

Lead Interface: The interface is used to connect with electrode wire (lead).

Screen Icons:

- LED icon will brighten while in Gait mode.
- LED icon will brighten while in Training mode.
- LED icon will brighten while the battery is low.
- LED icon will brighten while the electrode pad and wire is unconnected.
- 'L' icon means that this device used in Left leg.
- 'R' icon means that this device used in Right leg.
- Press and hold the "Composite Key", then turn on the Stim Unit. If

Frequently Asked Questions

1) What should I do while the icon " " appears on the Stim Unit's LED display?

The electrodes are frayed, peeling, damaged or falling off the Cuff. Replace or reconnect the electrodes.

2) What should I do while the icon " " appears on the Stim Unit's LED display?

The battery is low, and needs to replace.

3) What should I do if skin irritation or a skin reaction occurs under the area of the electrodes or Cuff?

- Stop using the XFT-2001 immediately.
- Contact your Clinician, Dermatologist or Clinical Specialist.
- Resume use only when the skin is completely healed.

4) What should I do if intensity of the stimulation is weaker at the parameter setting?

- The electrodes and/or skin need to be re-wet to improve conduction.
- Replace the Stim Unit batteries.
- Adjust the knob of intensity to a correct place.
- The cuff and electrode need to be shifted as the electrode placements are slightly off.

5) No stimulation despite the status LED is bright while in walking and training mode.

- Check the electrode leads to ensure that they are not broken.
- Check the electrode lead is firmly connected to the Stim Unit.
- Replace self-adhesive electrodes or enhance contact with water of gel.

6) How long does the electrodes can be used?

The electrodes should be changed approximately every 1-2 weeks, or immediately upon excessive wear.

7) What should I do if there is an occasional sharp stimulus?

The electrodes are old and need to be changed.
The electrodes are not wet enough.
Check skin under electrode for irritation or open areas.
Press firmly over each electrode to ensure to total contact with skin.
Ensure proper positioning of cuff and tighter the strap.

8) How long does the battery last?

The battery will last around 20 days (30 Mins per day), depending upon individual usage of the XFT-2001. A low battery is indicated by red flashing LED lights.

9) How should I do if I want to change the Pulse Width without using software?

Press and hold the "Composite Key", then turn on the Stim Unit. If the "Pulse Width" LED icon is brighten, then release the "Composite Key" will step into Pulse Width selection mode. While we press the Composite Key to select Pulse Width, the Pulse Width will blink to show. There are five kinds (25µs, 50µs, 100µs, 200µs and 300µs) of Pulse Width to choose. The icon blink once means the Pulse Width is 25µs, blink twice means 50µs, blink three times means 100µs, blink four times means 200µs, and blink five times means 300µs.

2. Electrodes

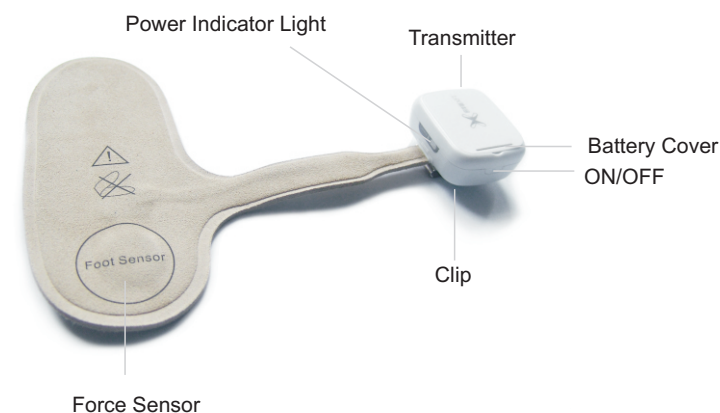
Electrode efficiency and durability depends entirely on the application, storage and care of the electrodes by the well-informed XFT-2001 user. The durability of the electrodes is dependent upon keeping the adhesive gel clean, hydrated and free from foreign debris. Other factors relating to electrode durability are skin condition, wearing environment, usage and climate. In all cases, the electrodes must be changed every 1-2 weeks (Or reused around 50 times) to maximize function and minimize the potential for skin irritation.

To obtain the most use from the electrodes, the following tips should be discussed and reviewed with the XFT-2001 user.

- Before applying the XFT-2001 system, the skin must be clean, dry and free from lotions or oils. Any debris on the skin will be transferred to the electrode compromising the adhesiveness and effectiveness of the electrode.
- When applying new electrodes, always lift the electrodes from the plastic backing at the edge.
- When removing the XFT-2001 from the leg, gently pull the cuff down and away from the leg in the same direction the hair lies. Never grasp the cuff and roughly pull away from the leg.
- Always cover the electrodes with the plastic backing when not in use. Be sure the 'on' side of the plastic piece is covering the gel.
- Always store and seal the unit in the provided storage bag and keep in a cool dry place when not in use. (Electrodes should be stored at temperatures of 5°C to 27°C. Do not store in the freezer/refrigerator, or leave in extreme heat.)

the "Pulse Width" LED icon is brighten, then release the "Composite Key" will step into Pulse Width selection mode. While we press the Composite Key to select Pulse Width, the Pulse Width will blink to show. There are five kinds (25 μ s, 50 μ s, 100 μ s, 200 μ s and 300 μ s) of Pulse Width to choose. The icon blink once means the Pulse Width is 25 μ s, blink twice means 50 μ s, blink three times means 100 μ s, blink four times means 200 μ s, and blink five times means 300 μ s.

3. Foot Sensor



The Intelli-Sense Foot Sensor detects when your foot is in the air or on the ground, and wirelessly signals the XFT-2001 to move your foot. The Foot Sensor including a force sensor and a transmitter. Place the force sensor into the shoe. And attach the transmitter to the inner rim of the shoe by using the clamp. The Foot Sensor can be transferred to a different shoe.

Operating Modes

1. Gait Mode

Select this mode for daily walking. In Gait mode the stimulation is synchronized by the Foot Sensor, in order to lift the foot when the heel leaves the ground and relax the foot after heel contact with the ground.

2. Training Mode

Select this mode for muscle training while you are sitting or lying down. The purpose of the Training mode is to facilitate muscle re-education, prevent or retard disuse atrophy of the lower leg muscles, maintain or improve range of motion of the ankle joint and improve local blood circulation. In the Training mode the stimulation is applied in pre-determined cycles adjusted by your clinician and works independently of the Foot Sensor.

 The Training mode can also be used to check if the Cuff was placed accurately on the leg. If the foot does not respond to the stimulation as it should, reposition the Cuff.

Care and Maintenance

1. Stim Unit and Cuff

Cleaning:

All parts may be cleaned by carefully wiping with a damp cloth. Electrical components are not waterproof, so do not immerse them in water. The Cuff is the only component that can be immersed in water for cleaning. When the Cuff needs a thorough cleaning:

- Remove the Stim Unit and electrode lead.
- Gently remove the Electrodes from the Cuff and store them on the Electrode Liners if they will be re-used.
- Immerse the Cuff for 30 minutes into lukewarm water with a small amount of mild detergent.
- Rinse thoroughly under running water.
- Immerse the Cuff for an additional 15 minutes into clean lukewarm water.
- Rinse again under running water.
- Blot excess moisture from the Cuff by gently pressing the surfaces with a towel. Do not wring the Cuff. Let dry in shade (do not hang). The Cuff should dry in 4 to 12 hours according to climate and humidity. To accelerate drying time place Cuff in front of a circulating cold air fan.
- Reattach the Stim Unit and Electrodes once the Cuff is completely dry.

 Do not use a washing machine, dryer or any other heat source to dry.

Storage:

When not being worn, the foot drop system (Cuff, electrodes, Foot Sensor and Stim Unit) should be stored in the carrying case in an area where temperatures 0 ~ 40°C. This will keep the electrodes from drying out. The XFT-2001 should be turned off when not in use and overnight to preserve the batteries and to allow the internal clock to function optimally.

Battery—If the XFT-2001 is to be stored for an extended period of time and not used, remove the battery from the battery compartment. When the batteries become depleted, please dispose of properly, in accordance with all local and national regulations. Do not use “bargain brand” batteries – regular AAA batteries and Coin batteries from a major manufacturer.

Disposal—When the device has reached the end of its useful life (5 years), please dispose of properly, in accordance with all local and national regulations.

7. Taking the Cuff OFF

- ⚠ The Cuff should be taken off the leg a few times during the day in order to allow the skin underneath it to "breathe". While the Remote Control and Stim Unit's batteries need to be replaced.
- ⚠ It is generally not necessary to trim body hair. If necessary, body hair should be trimmed with scissors rather than shaved in order to avoid skin irritation. Change Electrodes every two weeks to avoid skin problems.

- 1) Make sure the system is OFF.
- 2) Unfasten the Velcro strap at the back of the leg and slowly remove the Cuff by lifting the outer edge of the Cuff towards the center of the body and gently peel the Electrodes off the skin.
- 3) Place the Electrode covers over the Electrodes.
- 4) Store the Stim Unit, Remote Control, the electrodes and the peripheral nerve stimulator in carrying case.

8. Skin Care

Occasionally check the skin prior to and after using the XFT-2001. It is after using electrical stimulation for an extended period of time users may develop skin irritation or skin reaction under the site of the electrodes or the Cuff. XFT-2001 System users should follow these guidelines in order to ensure good skin health with increased dosage (wear time). It is important to develop a good skin care routine early and then continue to follow these guidelines when using the XFT-2001.

- To avoid crossing-infection of the skin diseases, the cuff and electrode should not be shared to use.
- Prior to putting on the Cuff for the first time each day, clean the surface of the skin that will be directly under the electrodes with a wet washcloth. If the skin has any oils or lotions, then it is best to clean it with soap and water and rinse well.
- Always check your skin in the area of the Cuff when putting on and taking off the Cuff (if necessary, another person can help you with this). Skin irritation or reaction usually appears in the form of redness or a rash.
- Make sure to maintain and replace your Electrodes whenever necessary. The electrodes should be replaced at least every two weeks even if they appear to be in good condition.
- After taking the Cuff off the leg, always cover the electrodes with their protective plastic covers.
- Excessive body hair in the area of the electrodes may reduce the electrode's contact with the skin. However, if shaving is necessary, then it is recommended that you use an electric shaver or scissors.
- Make sure the electrodes have uniform contact with the skin when the XFT-2001 is worn.
- If the XFT-2001 is used continuously all day along, then you should ventilate the skin by taking off the Cuff for at least 15 minutes approximately every 2-3 hours.
- If skin irritation or a skin reaction occurs:
 - STOP using the XFT-2001 immediately.
 - CONTACT your Clinician, Dermatologist.
 - RESUME use only when your skin is completely healed
 - Once you resume use of the XFT-2001, follow the clinical recommendations from your Clinician, Dermatologist.

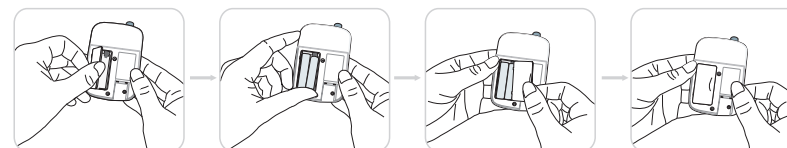
Daily Use of Your XFT-2001

1. Installing and Replacing the Batteries

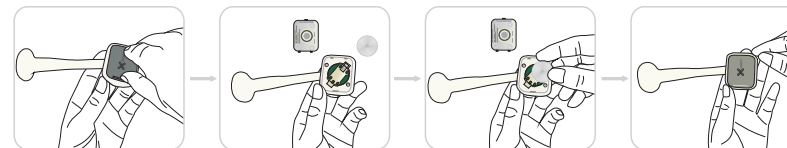
The expected battery life (The Stim unit) is about 11 hours of continuous use. Dependent upon the use, the batteries could last from 1 to 2 weeks. When the intensity of the stimulation is weak or the "🔋" icon is bright, it means that the battery should be replaced immediately. The expected battery life of Foot Sensor is about 2 hours of continuous use.

- 1) Make sure the system is OFF. To replace the battery, grip the sides of the cover to the battery compartment and pull open.
- 2) Insert AAA batteries and coin battery (LIR2450) into the device (Pay attention to the "+" towards).
- 3) Close the batteries cover.

Stim Unit



Foot Sensor

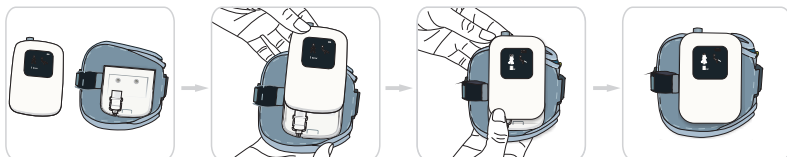


※ Note: When the battery becomes depleted, please dispose of the battery properly in accordance with all local and national regulations.

2. Installing the Stimulation Unit onto the Cuff

Make sure the system is OFF before installation.

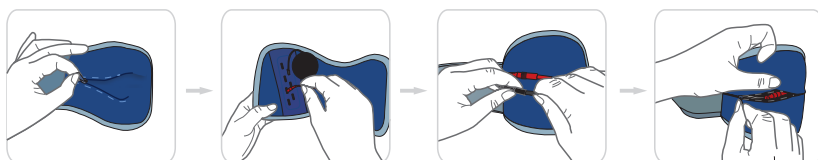
- 1) Let the electrode lead cross the cuff through its hole.
- 2) Slide the stim unit onto the cuff.
- 3) Complete.



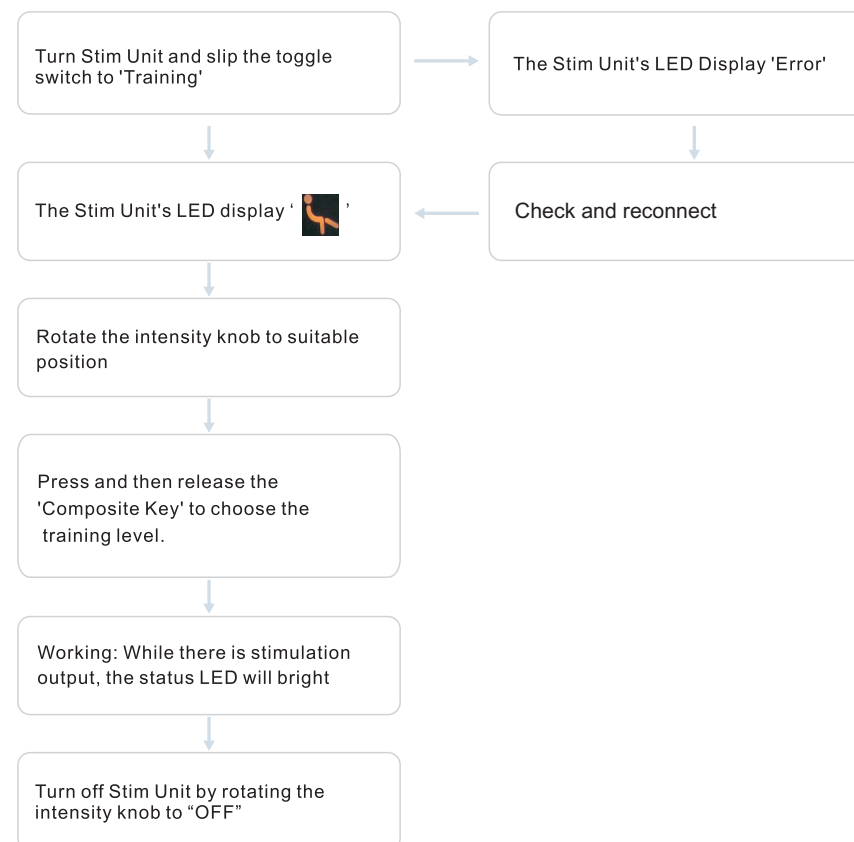
3. Connect and Replace the Electrode Pads

⚠ For proper skincare and maximum effectiveness, the electrodes should be replaced every 1 to 2 weeks. The XFT-2001 should only be used with Electrodes supplied by XFT. Do not use the XFT-2001 without Electrodes

- 1) Make sure the system is OFF.
- 2) Unzip and let one side of electrode lead cross the cuff through its hole.
- 3) Connect the electrodes to the other side of the cable. The RED lead is connected to the RED Electrode; the BLACK lead is connected to the BLACK Electrode.
- 4) Rearrange the electrode wire and zip up.




- 3) Press the 'Composite Key' and release, you can choose training level 1 (Meanwhile the Training LED icon will blink one time); While you press the button at the fifth time, the training level will be level 5 (Meanwhile the Training LED icon will blink 5 times continuously); While you press the button at the sixth time, the training level will be back to level 1 (Meanwhile the Training LED icon will blink one time).



6.3 Training Mode

Select this mode (Slip the toggle switch to 'Training') for muscle training while you are sitting or lying down. Most often, it is used at the end of the day once most of the user's walking activities have been performed. The purpose of the Training mode is to facilitate muscle re-education, prevent or retard disuse atrophy of the lower leg muscles, maintain or improve range of motion of the ankle joint and improve local blood circulation.

- The Exercise Mode may be helpful during or after the donning process to verify correct electrode placement.
- Some users may benefit from using the Exercise Mode to 'warm up' the neural pathways prior to walking.
- For some users, a lower intensity setting on the XFT-2001 is used for exercising than for walking. Users may occasionally assist the exercise stimulation by actively dorsiflexing the foot.
- Adjusting the Training Settings:

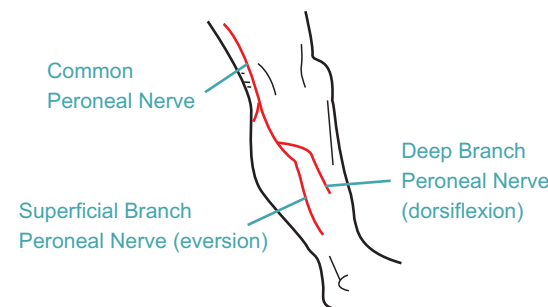
- 1) Turn on the Stim Unit. Slip the toggle switch to 'Training'. The Stim Unit's LED will display .
- 2) Press 'Composite Key' on the Stim Unit to choose the training level. There are 5 levels for choice.

Training Mode Parameters (Default Mode)

Level	On Time (Second)	Off Time (Second)
1	1.5s	3s
2	2s	4s
3	2.5s	5s
4	3s	6s
5	3.5s	7s

4. Identify Initial Placement of the Posterior Electrode

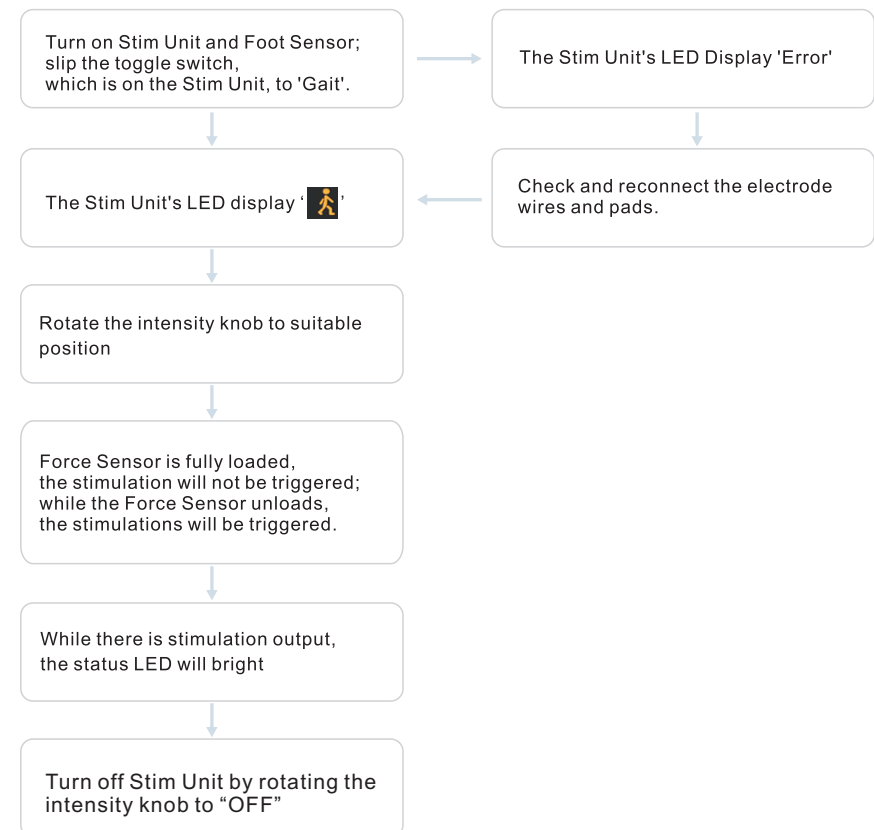
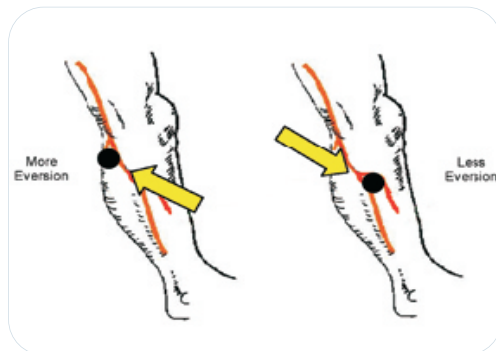
The clinician will find the best stimulation areas and set the initial placement of the electrode to produce a 'balanced' dorsiflexion and eversion movement of the foot/ankle. And, we also can use it to determine the viability of the common peroneal nerve and the degree of innervation of the peroneus longus (superficial branch) and tibialis anterior (deep branch) muscles. All the testing procedure must be operated by a professional clinician.



4.1 Electrode Placements and Final Preparations for Walking


- 1) Make sure the XFT-2001 (Stim Unit) is turned OFF and attach the electrode lead to the back of the XFT-2001. This allows plenty of lead length to attach the electrodes and also prevents excessive bending or flexing of the electrode lead.
- 2) Attach the XFT-2001 to the cuff on the medial flattened area. Position the cuff around the mid-calf region and secure in place below the potential electrode sites. This places the XFT-2001 in a convenient location to hook up the electrodes.
- 3) Saturate the surface of the gel electrode with water. Place the back electrode over the mark identified during the testing procedure with the peripheral nerve stimulator and the front electrode on the upper 1/3 of the tibialis anterior muscle belly. Be sure to keep the vertical spacing of the electrodes within the width allowance of the XFT-2001 cuff.
- 4) The ABC's of Electrode Placement:
 - Accuracy of electrode placement when fitting the XFT-2001 system is the key to the efficient, comfort and functional control of foot lift. 'Balanced' placement of the electrodes promotes a safe and symmetrical gait while preserving muscle endurance. The closer the black (posterior) electrode is to a position directly over the motor nerve, the more comfortable the stimulation is for the user as precise positioning of the electrodes lessens the sensory response to the stimulation. The more precise the electrode placement, the stronger the muscle contraction at lower levels of intensity. The goal of electrode placement is to produce the most functional movement at the lowest intensity level so that the risks of muscle fatigue or skin irritation are minimized.

- “Black to the back and red ahead” is the key phrase to remember when connecting the electrodes. The black electrode is negative and sends the stimulation into the leg. The red electrode is positive and forms a complete circuit to pull the stimulation out of the leg. The stimulation is optimized if it enters at the motor nerve and exits after traveling in the direction of the muscle.
 - Conductivity is enhanced by a complete circuit and by assuring a uniform electrode-skin interface. Apply plenty of water to the electrodes (and the skin if desired); make sure that there is no water between the electrodes. Spacing of the electrodes will also affect conduction of the stimulus signal:
 - The closer the electrodes, the more superficial the current = more eversion
 - The farther apart the electrodes, the deeper the current = more dorsiflexion
- 5) The black electrode determines the direction of the foot lift by stimulating the superficial and/or deep branches of the common peroneal nerve. Generally, shifting the black electrode more posterior and proximal elicits more eversion; and shifting the black electrode more anterior and distal elicits more dorsiflexion. Keep in mind that anatomical variations are common and methodical exploration of the user's leg will identify the most appropriate electrode locations.



6. Activating and Using the System

6.1 Activating the System


 It needs to be operated by qualified clinician when it is used for the first time. The patient needs to follow the clinician's advices to operate it.

- 1) Position the Cuff on your leg.
- 2) Turn on the Stim Unit and Foot Sensor. While the Power Indicator Light on the Foot Sensor blinks, and there are two 'Beeps' to alarm. It means that the Stim Unit and Foot Sensor connect successfully.
- 3) Select either Gait or Training mode as needed.
 - a. Begin walking if Gait mode is selected.
 - b. Execute your exercises if Training mode is selected.

6.2 Gait Mode

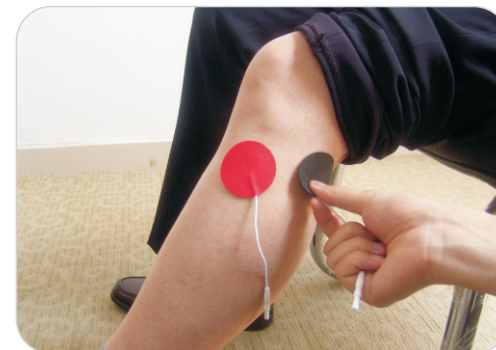
The user can use the device in daily walking in gait mode.

Stimulation Triggered by Foot Sensor

- 1) Rotate the intensity knob to turn on Stim Unit. Slip the toggle switch to 'Gait', and adjust the intensity as required. The Stim Unit's LED display will show the icon .
- 2) Place the Force Sensor under the shoe insole, and clip the transmitter on the upper edge of the shoe. Turn on the Foot Sensor. If its Power Indicator Light blink, and then two 'Beeps' to alarm; it means that the Foot Sensor has connected successfully with the Stim Unit.
- 3) When the patient walks, the XFT-2001 will work in Foot Sensor trigger stimulation mode. While the Force Sensor is fully loaded, the stimulation will not be triggered; while the Force Sensor unloads, the stimulations will be triggered.
- 4) Rotating the intensity knob to "OFF" to turn off the Stim Unit and turn off the Foot Sensor while the users do not use it.

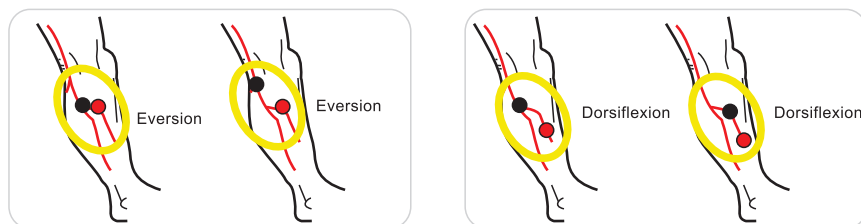
 After walks more than 24 steps with Foot Sensor (Essential condition) in gait mode, users can also use Tilt Sensor to trigger stimulation by turn off the Foot Sensor.

- 6) Connect the electrodes to the XFT-2001 electrode lead. Make sure the BLACK lead (negative) is connected to the BACK electrode and the RED lead (positive) is connected to the FRONT electrode.



- 7) Turn the XFT-2001 ON by turning the Intensity Knob in a clockwise direction to the 0 (on) position. A LED icon will light to indicate that the unit is on. ALWAYS start at a low level of intensity and gradually increase during the testing procedure.
- 8) Turn on the XFT-2001, press 'Composite Key' on the Stim Unit in Gait mode to initiate the stimulation. A light next to the 'Composite Key' on the Stim Unit will appear to indicate that the unit is stimulating. In Gait Mode, press and hold Composite Key 1-2 seconds to determine if the electrode placement is optimal. Watch and palpate the muscles of the lower leg that produce foot lift. Gradually turn up the intensity if the movement produced is too small or shift the electrodes and try again. Even a small shift of the electrode may change the amplitude or direction of the foot movement (for example, from dorsiflexion to eversion with more recruitment of the peroneals). The goal is to produce an effective foot lift with as low stimulus intensity as possible. Note the numerical value of the intensity used to produce an effective dorsiflexion movement.

9) Anatomical variations may include.



- 10) Evaluate the amount and direction of pressure provided by the hand covering the electrodes during the stimulus testing procedure. In some cases, distinct and specific pressures are required to obtain and maintain good communication with the nerve. To obtain the same outcome, this same pressure must be duplicated when placing the XFT-2001 cuff over the electrodes.
- 11) Once the optimal electrode positions have been found, turn off the XFT-2001, release the strap and properly align the cuff over and around the pretibial region. Press on the area of the cuff covering the electrodes to ensure that the Velcro backing on the electrodes adheres to the inside of the cuff. However, an adjustment of electrode placement often negates the need for custom fitting of the cuff.
- 12) Place the Force Sensor under the insole, at the heel of the shoe, in the user's shoe on the affected side. Turn on the Foot Sensor to connect with the XFT-2001 unit (The Stim Unit also should be turn on) by Bluetooth.
- 13) Turn the XFT-2001 ON and adjust the intensity to the same level determined during initial fitting. It is a good idea to test the stimulation after the person has stood up and obtained their balance to ensure a functional foot lift is produced prior to walking.
- 14) Upon final delivery of the XFT-2001, the electrode placements should be marked inside the cuff by clinician. This will make it easier for the user to change the electrodes without losing the appropriate placement of the electrodes inside the cuff. Final markings should only be done after all adjustments and walking trials have been completed.

5. Positioning the FS Cuff on Your Leg

⚠ It needs to be operated by qualified clinician when it is used for the first time. The patient needs to follow the clinician's advices to operate it.

- 1) Clean the surface of the skin with a wet washcloth. If the skin has any oils or lotions it is best to clean it with soap and water, and rinse well.
- 2) Before using the system makes sure the device is OFF.
- 3) While seated, slightly straighten your leg. It may be helpful to place your foot on a small stool or footrest.
- 4) Positioning the Cuff correctly (Location label align with tibias) on the leg, and then fastening the strap.

